

STANDARD MEDICARE PART B MANAGEMENT

ANDEXXA (coagulation factor Xa (recombinant), inactivated-zhzo)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Andexxa is indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

B. Compendial Use

Reversal of edoxaban or betrixaban anticoagulation due to life-threatening or uncontrolled bleeding

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Reversal of direct-acting oral anticoagulant due to life-threatening or uncontrolled bleeding

Authorization of one course of therapy (i.e., consisting of an initial intravenous (IV) bolus and a follow-on IV infusion) may be granted for treatment reversal of direct-acting oral anticoagulant (i.e., Factor Xa inhibitor) when both of the following criteria are met:

- A. The member is receiving rivaroxaban, apixaban, edoxaban, or betrixaban for anticoagulation.
- B. The member is experiencing life-threatening or uncontrolled bleeding due to a Factor Xa inhibitor (i.e., rivaroxaban, apixaban, edoxaban, or betrixaban).

III. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Andexxa.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology

3. 2020 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants: A Report of the American College of Cardiology Solution Set Oversight Committee

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Andexxa are covered in addition to reversal of edoxaban or betrixaban anticoagulation due to life-threatening or uncontrolled bleeding.

IV. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Andexxa to treat life-threatening or uncontrolled bleeding due to edoxaban or betrixaban can be found in the 2020 American College of Cardiology Expert Consensus Decision Pathway on Management of Bleeding. High-dose Andexxa is recommended to reverse bleeding for betrixaban and edoxaban. If Andexxa is not available, the use of prothrombin complex concentrate (PCC) or activated PCC is recommended.

V. REFERENCES

1. Andexxa [package insert]. South San Francisco, CA: Portola Pharmaceuticals, Inc.; July 2022.
2. Cuker A, Burnett A, Triller D, et al. Reversal of direct oral anticoagulants: Guidance from the Anticoagulation Forum. *Am J Hematol*. 2019;94:697-709. <https://doi.org/10.1002/ajh.25475>.
3. Tomaselli GF, Mahaffey KW, et al. 2020 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2020 Aug 4;76(5):594-622. <https://doi.org/10.1016/j.jacc.2020.04.053>.